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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 751,654	12 29 2000	Sergei G. Bavykin	0003 00797	8872

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06 03 2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/751,654

Applicant(s)

BAVYKIN ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No.109) filed on March 6, 2002 has been entered.

Response to Arguments

2. Applicant's response to the office action (Paper No.10) is fully considered and deemed persuasive in part.

3. The objection made in the previous office action with respect to color drawings is withdrawn herein in view of Applicants' submission of substitute black/white drawings (Paper No. 11).

4. The objection made in the previous office action with respect to Oath/Declaration is withdrawn herein in view of Applicant's submission of substitute Oath/Declaration (Paper No. 10).

5. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.10).

6. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicant's arguments with respect to claims 1,3,4,8, 11 and 13-14 are considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5-6, 8-20, 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The instant claims vague and unclear for being reciting the term "manipulating" genetic material, because it is unclear what it accomplishes for. The method steps recite isolation or extraction of genetic material but not manipulate genetic material by recombinant techniques. Amendment to properly recite the invention would obviate the rejection.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekenberg (USPN. 6,218,531) in view of Proudnikov et al. (Nucleic Acids Res., vol. 24(22): 4535-4532, 1996).

Ekenberg teaches a method for isolating genetic material wherein the method comprises (i) disrupting cells to liberate genetic material contained in the cells with guanidine

isothiocyanate-containing buffer (see column 7, lines 26-40); (ii) contacting the genetic material to a column in a manner to cause the genetic material to become immobilized to the column (see column 7, lines 48-52); and eluting the genetic material from the silica column (see column 7, lines 53-65). Ekenberg also teaches more than one buffer system comprising a lysis buffer, dilution buffer, and elution buffer (see column 7, lines 26-42); the process takes less than 1 hour, and more preferably less than 20 minutes (see column 9, lines 14-23); lysis buffer contains guanidine thiocyanate (see column 17, lines 29-35) and elution buffer contains EDTA (see column 16, lines 48-65); pressure is applied to elute the genetic material from the column (see column 20, lines 14-55); the process is maintained between 30- 100 °C (see column 18 lines 4-23), However Ekenberg did not teach labeling the genetic material in the column.

Proudnikov et al. teach a method for labeling genetic material in a column wherein Proudnikov et al. teach loading the genetic material in a column and labeling the genetic material in the column by creating radical generating group on the genetic material and attaching a chromophore (see page 4537, column 1, paragraph 1 and page 4536, column 1, paragraphs 5-7, and 4538, column 1, and paragraph 1) Proudnikov et al. also teach the labeling of genetic material was carried out at 37 °C (see page 4537, column 1, paragraph 2) and the labeling is done in anaerobic (in the column) or aerobic conditions (out side the column) (see page 4536, column 2, paragraph 4, and page 4537, column 1, paragraph 1-2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of isolating genetic material from cells as taught by Ekenberg with the method of labelling as taught by Proudnikov et al. because Ekenberg states that "the genetic material obtained from this procedure can be used for analysis or further

processing by molecular biological procedures and can also be used for nucleic acid probe hybridization (see page column 17, lines 1-12). One such alternative form of sensitive processing applications, expressly motivated by Proudnikov et al. is the use of labeling the genetic material in the column process.

Further, selection of specific temperature and buffer ratios represents routine optimization with regard to isolation of genetic material, which routine optimization parameters are explicitly recognized in Ekenberg and Proudnikov et al. As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of specific temperature and ratios of buffer solutions performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

An ordinary practitioner would have been motivated to combine the method of Ekenberg with the method of Proudnikov et al. in order to achieve the expected advantage of a rapid and sensitive method for labelling a nucleic acid.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 1637

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
May 31, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER